REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

I. Claim Status

Claim 26 is amended and claim 34 is added. No claims are cancelled.

Support for the revisions to claim 26 and new claim 34 is evident throughout the specification. Thus, support for the revisions to claim 26 can be found on page 3, line 28 – page 6, line 28, and for new claim 34 on page 8, line 16 – page 10, line 5 and in Figure 14.

It is apparent, therefore, that the above-discussed changes introduce no impermissible new matter and, hence, that entry of the changes is appropriate. Upon such entry, claims 26-34 will be pending and subject to examination on the merits.

II. Substance of Examiner Interview

Pursuant to a request in the Examiner's Interview Summary dated September 20, 2011, applicants provide the timely response that the Summary document accurately capsulizes the interview.

III. Section 102 Rejection To Claims 26-33 Should Be Withdrawn

Claims 26-33 stand rejected for alleged anticipation by Sair, U.S. 4,230,687, as evidenced by Wheat Flour (http://en.wikipedia.org/wiki/Flour). Yet Sair discloses or suggests neither the homogenizing of a mixture, thereby to obtain an agent-in-water emulsion, nor the product resulting from the process, as recited in claim 26.

More specifically, independent claim 26 is directed to a material for encapsulating a therapeutic and nutritional agent, which is storage unstable. The material of claim 26 is produced by a process that includes the steps of "treating a starch to increase the number of sugar reducing groups in the resulting treated starch;" and then "forming a dispersion of a film forming protein and the treated starch in an aqueous phase." The forming step is followed by "mixing the agent with the dispersion to form a mixture" and then "homogenizing the mixture to obtain an agent-in-

water emulsion, such that the treated starch and the film forming protein form a protective shell around the agent during the homogenizing step, which shell allows release of the agent in the gastrointestinal tract."

This methodology ensures that the mixture is homogenized to obtain an agent-in-water emulsion. Specification at page 6, lines 24-26. The emulsion protects the agent against early uptake and metabolism in the stomach and upper gastrointestinal (GI) tract. *Id.* at page 3, line 28 – page 6, line 28. If the agent, film forming protein, and treated starch are not so homogenized to obtain an agent-in-water emulsion, then the treated starch and film forming protein do not form a protective shell around the agent. *Id.* Such a failure results in release of agent before it reaches the GI tract, thereby preventing the delivery there of essential components. *Id.* at page 1, lines 23-29.

While acknowledging that "the method disclosed by Sair et al. is not exactly the same as the claimed...method," the examiner contends that "the encapsulation material disclosed by Sair et al. and the claimed encapsulation material comprise the same components with the components being physically mixed, thus the product disclosed by Sair et al. would necessarily be the same as the claimed product." Office Action at pages 3-4.

The accompanying Declaration Under 37 C.F.R. § 1.132 of Mary Ann Augustin ("Augustin Decl.") demonstrates, however, that the product of Sair's process is wholly dissimilar from the product of the presently recited process. The declarant, an expert in the field of the invention, attests "the process recited in claim 26 results in a material that forms a protective shell around an agent, while the process disclosed in Sair fails to produce such an effect." Augustin Dec. ¶ 11. It is the declarant's "understanding that the process of claim 26 produces the aforementioned material because the mixture of film forming protein, treated starch and agent is homogenized to obtain an agent-in-water emulsion" while "Sair does not produce the aforementioned material because Sair counsels using relatively little water so as *not* to form an emulsion." *Id.*

In aid of substantiating this expert assessment, the declarant also "conducted experiments that compared the product resulting from the process prescribed in claim 26 to that of the process disclosed in Sair" and attached the experimental results as Exhibits B-D to the declaration. *Id.* at

¶ 6. "Each of Exhibits B – D contain four figures" where "[f]igures 1 and 2 show the material that results when the formulation with casein and Hylon VII undergoes the process recited in claim 26 and disclosed in Sair, respectively...[e]ach of Figures 3 and 4 (Exhibits B – D) shows the material that results when the formulation of Sair's Example 1 (casein) and the formulation of Sair's Example 25 (Capsul) respectively undergo the process disclosed in Sair." *Id.* at ¶ 7.

The declarant states that "Figure 1a shows that material resulting from the process of claim 26 is spherical because the treated starch and film forming protein form a protective shell around the agent" while "Figures 2a-4a show that the process used in Sair yields material characterized by an irregularly shaped and non-spherical structure, resembling a sheet" such that the process used in Sair "does not result in a protective shell formed around an agent. *Id.* at ¶ 8. Similarly, "Figure 1b shows a homogenized distribution, where relatively little non-encapsulated agent results from the process of claim 26" while Figure 2b "depicts an inhomogenous distribution where a large number of non-encapsulated agent result from the process disclosed in Sair.' *Id.* at ¶ 9. Like Figure 2b, Figures 3b and 4b show a large number of non-encapsulated agent. *Id.* The declarant attests that Figures 1c-4c further substantiate that the product resulting from the process prescribed in claim 26 is different from that resulting from the process disclosed in Sair. The declarant further states that, as is "evident from Figure 1c, the product resulting from the process recited in claim 26 is a free flowing powder that has no oil leakage. In contrast, Figures 2c-4c show that material resulting from the process of Sair is an oily powder, displaying oil leakage." *Id.* at ¶ 10.

Pursuant to the results documented by the declarant, therefore, the product resulting from the process prescribed in claim 26 indeed differs substantially from the product resulting from the process used in Sair. A rejection of claim 26 over Sair cannot stand, therefore, and the claims depending from claim 26 likewise are patentable over the art of record.

CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Yu also is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.